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**UNITED STATES DISTRICT COURT**

**FOR THE NORTHERN DISTRICT OF CALIFORNIA**

**SAN FRANCISCO DIVISION**

IN RE: DA VINCI SURGICAL ROBOT ANTITRUST LITIGATION

THIS DOCUMENT RELATES TO:

ALL ACTIONS

Case No.: 3:21-cv-03825-AMO-LB

**REPLY BRIEF OF INTUITIVE SURGICAL, INC. ON CROSS-MOTIONS FOR SUMMARY JUDGMENT**

Hearing To Be Renoticed
Place: Courtroom 10

Judge: The Honorable Araceli Martínez-Olguín

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## I. INTRODUCTION

Under the Food, Drug & Cosmetic Act, a Class II medical device requires appropriate measures to provide "reasonable assurance of safety and effectiveness." 21 U.S.C. § 360c(a)(1)(B). Implementation of this mandate through other statutory provisions and regulations includes a requirement that the manufacturer (or remanufacturer) of a device submit to FDA a "510(k)" submission providing extensive information about the device's design and operation, along with testing data to demonstrate its safety and effectiveness. FDA must then "clear" the 510(k) submission before hospitals may lawfully use the devices on patients in a clinical setting. *See* Intuitive Opp. and Cross-Motion (Dkt. No. 153) ("CM") at 14-15. ***These core elements of the regulatory regime are undisputed here.***

Notwithstanding the array of factual assertions in plaintiffs' briefs, it is also undisputed that: (a) the EndoWrists used with da Vinci systems are Class II medical devices; (b) because of their unique design and construction, EndoWrists cannot be used indefinitely before they are at substantial risk of failure, endangering patient safety; and (c) the demonstration of safety and effectiveness for EndoWrists that FDA cleared encompassed use counters that disable the device after a specified number of uses. *Id.* at 3-5, 14-15. On the last of these points, plaintiffs argue that the use counter was not FDA's idea originally and that it is not the *best* way to assure the instruments' safety and effectiveness, but they do not, and cannot, contest that: (a) some form of protective measure is needed, (b) use counters, and the use limits they implement, were encompassed within the 510(k) submissions that FDA cleared, and (c) FDA has subsequently treated them as a crucial element of that clearance. *Id.*

It is also undisputed that "remanufacturing" a Class II medical device is unlawful absent FDA clearance and that FDA has repeatedly and consistently stated that modification of an EndoWrist to bypass its use counter to add uses constitutes "remanufacturing." *Id.* at 15. Plaintiffs attempt to dissect and discount individual FDA communications on the subject and then, failing all else, to distract attention with "evidence" such as transparently double hearsay reports from a Wall Street financial analyst. But they cannot escape the consistency of FDA's position. And plaintiffs have failed to present a persuasive *legal* argument for concluding that FDA is wrong. They do not dispute that FDA clearance is required if the activity at issue is properly characterized as "remanufacturing." And they cannot duck the "remanufacturing" label FDA has correctly applied by simply *calling* it "repair."

Given these undisputed facts, plaintiffs' Sherman Act claims fail as a matter of law. It is well established in this Circuit that antitrust injury – a mandatory element of every antitrust claim – cannot be premised on the plaintiff's inability to engage in unlawful activity. *See id.* at 13-14 (citing cases). Plaintiffs' response that FDA never *enforced* the law against EndoWrist remanufacturers who lacked FDA clearance is both inaccurate factually and unavailing legally. Nor can antitrust injury be premised on speculation (or proof, if it existed) that market participants would have been willing to flout the law.

Plaintiffs also have no persuasive answer on another mandatory element of their claims: proof of a substantially less restrictive alternative. *See Epic Games, Inc. v. Apple, Inc.*, 2023 WL 3050076, at *24 (9th Cir. Apr. 24, 2023). Intuitive has identified clear regulatory and procompetitive justifications for the challenged restraints. CM at 4-5, 22-24. Contrary to plaintiffs' argument, such justifications provide a valid antitrust defense in the Ninth Circuit. Plaintiffs' mere *assertion* that the use limits were not "endorsed" by FDA cannot contradict the plain statements and actions of FDA itself. Nor are plaintiffs' dark references to profit motives sufficient to undermine FDA's insistence that the use limits have so important a role in protecting patient safety that no one – including even Intuitive itself – may change the use limits without making a *separate* safety demonstration that satisfies the agency. Under the Ninth Circuit's recent decision in *Epic Games*, the burden is therefore on plaintiffs to establish the existence of a substantially less restrictive alternative that is equally as effective in satisfying the legitimate purposes of the challenged restraints. Plaintiffs' vague references to other hypothetical methods of dealing with instrument failure fall far short of satisfying that standard.

Plaintiffs' cross-motion for partial summary judgment on the FDA regulatory/antitrust injury issue should be denied for the same reasons Intuitive's motion on that same issue should be granted. And plaintiffs' motion for summary judgment on issues of market definition and market power is easily rejected based on the numerous disputed issues of material fact that exist on those points.

## II. ARGUMENT

In opposing Intuitive's motion for summary judgment, plaintiffs had a duty to establish the existence of genuine disputes of material fact. *In re Oracle Corp. Sec. Litig.*, 627 F.3d 376, 387 (9th Cir. 2010). The dispute must be about *fact*, not about the law. *Coomes v. Edmonds Sch. Dist. No. 15*, 816 F.3d 1255, 1261-62 (9th Cir. 2016). And the fact must be *material* – not one that is "irrelevant or

unnecessary," but rather one that "might affect the outcome of the suit." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). Last but not least, the dispute must be *genuine* – i.e., it must arise from a significant conflict in the (admissible) evidence presented. *Elam v. Nat'l R.R. Passenger Corp.*, 220 F. Supp. 3d 996, 1000-01 (N.D. Cal. 2016) (citing *Anderson*, 477 U.S. at 248-50); *see also In re Oracle*, 627 F.3d at 385, 387 ("The non-moving party must do more than show there is some 'metaphysical doubt' as to the material facts…." (quoting *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986))). A mere "scintilla" of evidence is insufficient. *Anderson*, 477 U.S. at 252.

Conversely, in pressing their own motion for summary judgment, plaintiffs cannot merely respond to Intuitive's showing of genuine disputes of material fact by asking the Court to resolve those disputes in their favor; their motion must be denied unless they can show entitlement to judgment as a matter of law based on *undisputed* facts. *Elam*, 220 F. Supp. 3d at 1000-01.

Plaintiffs have failed to satisfy their burden on either score.

### A. Plaintiffs Have Not Established the Existence of Disputed Issues of Fact That Are Material to Intuitive's Cross-Motion.

The factual discussion with which plaintiffs begin their Reply (at 1-5) identifies no genuine disputes of material fact; rather, it offers a series of straw-man arguments.[1] Plaintiffs make much, for example, of evidence that EndoWrists occasionally fail before reaching their use limits, proclaiming that the record "does not support Intuitive's claim that its preset use limits prevent EndoWrist failures." Pl. Rep. at 3. Intuitive has never made any such claim. Nor have plaintiffs identified any alternative control mechanism that would provide such an unrealistic guarantee. Medical technology must focus on *managing* risks, which can rarely be eliminated entirely. The record is clear that EndoWrist use limits were set, based on statistical analysis of detailed testing results, to manage the risk of instrument failure to a level that FDA, after careful review, has deemed acceptable. *See* Rosa Dec. (Dkt. No. 153-2) ¶¶ 23, 31. And the fact that the rare instances of instrument failure have only even more rarely resulted in

[1] Intuitive will focus in this brief on the absence of *genuine* disputes of *material* fact. Intuitive's failure to address a particular assertion made by plaintiffs should not be construed as agreeing that plaintiffs' characterization of the cited evidence is accurate – it often is not – or as a waiver of evidentiary objections for purposes of other proceedings in this case.

serious harm to patients (Pl. Rep. at 3) merely attests to Intuitive's success in managing these risks. In short, there is no genuine dispute of *material* fact on these points.[2]

Plaintiffs also stress that FDA was not the *original* source of the idea of the EndoWrist use counter. Again, this is a straw-man argument. Under the applicable regulatory regime, it was Intuitive's obligation in the first instance to propose specific measures that would provide the required "reasonable assurance of safety and effectiveness." 21 C.F.R. §§ 860.7(b), 860.7(c). That is what it did, and its 510(k) submissions identified and described the use counter as a measure to address risk of failure and resulting potential for patient harm. But that was not the end of the story: FDA then reviewed the measures Intuitive proposed and the supporting data and cleared the instruments in the form Intuitive had described – which included the use counter – as eligible for distribution and use on patients. Plaintiffs repeatedly quote a single sentence in one internal Intuitive email saying, "Just so you know, FDA does not require nor limit the number of uses for our EW instruments." Pl. Rep. at 1, 5, 7 (citing Corrigan Dec. (Dkt. No. 149-1) Ex. 33). But the next sentence explains: "During the 510(k) submission process, we provide data to FDA that supports the stated number of lives for a particular instrument that we state in our labeling." Corrigan Dec. Ex. 33. FDA then reviewed and cleared this showing to authorize the instruments to be used on patients. *See* Rosa Dec. ¶¶ 23, 31.

Critically, plaintiffs ask the Court to ignore entirely the fact that, as FDA has repeatedly explained (and as the undisputed record shows), any modification of an EndoWrist to bypass the use counter causes the instrument to "no longer maintain the same safety and effectiveness profile as cleared with the original manufacturer's own submission." Cahoy Dec. Ex. 64 at -5727. In short, as FDA has explained, "if the use-life counter is reset or extended past the number of available use lives, *then the device specifications are changed*." *Id.* Ex. 31 at -0335 (emphasis added). This makes the reset process remanufacturing, which requires separate FDA clearance – not just because FDA says so (as it has

[2] Another straw-man argument is that Intuitive's testing is not "exhaustive" – which plaintiffs construe as consisting just of testing "to failure." Pl. Rep. at 2. In fact, the record confirms that the extensive testing data Intuitive gathered included points at which EndoWrists failed. Cahoy Dec. (Dkt. No. 153-8) Ex. 3 ¶ 71; Rosa Dec. ¶¶ 28-32. Intuitive applies sophisticated statistical analysis to the testing data to confirm that limits are responsibly set. Cahoy Dec. Ex. 3 ¶ 72. Intuitive also tracks data on instrument returns through the return material authorization ("RMA") process; that data confirms the accuracy of the life testing. *Id.* ¶¶ 73-76; *see also* Rosa Dec. ¶ 40.

consistently done) but because that is what the governing law requires. *See id.*; 21 C.F.R. §§ 807.81(a)(2), 820.3(w); *see also* 21 U.S.C. § 360(k); 21 C.F.R. §§ 807.81(a)(3), 807.20(a), 820.3(o).

### B. Plaintiffs Cannot Demonstrate Antitrust Injury on Their Claims Relating to "Competition" from Remanufactured EndoWrists.

#### 1. Antitrust Injury Cannot Arise from the Absence of Unlawful Competition.

Contrary to plaintiffs' assertion (Pl. Rep. at 5), Intuitive *does* contest that their alleged "injuries" were of a type the antitrust laws were intended to prevent. The law is clear in this Circuit that the antitrust laws were not intended to permit a plaintiff to recover damages for its inability to pursue an unlawful activity. Plaintiffs do not even *mention* the numerous decisions Intuitive has cited from the Ninth Circuit and multiple judges on this Court confirming this principle. *See* CM at 13-14. Instead, they point only to two decisions from Florida that do not apply Ninth Circuit law. Plaintiffs' silence about case law from this Court and the Ninth Circuit speaks volumes.[3]

Plaintiffs do concede, citing a decision from the Third Circuit, that their claims would be barred if the "competition" they claim should have occurred was "effectively blocked" by law. Pl. Rep. at 7.[4] But they argue that this rule does not apply here because, regardless of what the law *says*, FDA did not take action to *enforce* the law against EndoWrist remanufacturers. Absent that, plaintiffs speculate, companies like Rebotix might have continued to flout the law and provide "competition." This argument ignores both the undisputed facts and the law on antitrust injury.

To begin with, plaintiffs offer no analysis of the statute or governing regulations to dispute that the law itself requires 510(k) clearance here. In its opening brief (CM at 14-15), Intuitive identified the regulations that define when a particular activity is "remanufacturing" and explained how hacking into an EndoWrist use counter to bypass the use limits fits that definition. Plaintiffs do not try to show otherwise but instead argue that the regulations do not apply to them because (a) FDA never issued an

[3] Plaintiffs also do not address the recent on-point decision in *PharmacyChecker.com v. Nat'l Ass'n of Bds. of Pharmacy*, 2023 WL 2973038 (S.D.N.Y. Mar. 28, 2023). There, the plaintiff claimed the defendants had violated the antitrust laws by interfering with its business of facilitating consumers' ability to order drugs from foreign pharmacies. The Court found the importation of prescription drugs to be illegal under the FDCA and FDA regulations; as a result, it held the plaintiff could not demonstrate antitrust injury and granted summary judgment for defendants. *Id.* at *20-24, *30.

[4] Plaintiffs do not discuss *In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132 (3d Cir. 2017), from which they lifted the words "effectively blocked." That decision makes clear that consumer plaintiffs bear the burden of showing their claims rest on a lawful activity. *Id.* at 165-66.

official "guidance document" confirming that the law applies to EndoWrists, and (b) FDA took no steps to *enforce* a requirement that remanufacturers of EndoWrist use counters obtain 510(k) clearance. The first of these is equivalent to saying that a law banning speeding at 100 mph will not apply to drivers of the newest Tesla model unless the government issues an official "guidance document" confirming that the speed limit applies to Teslas. The second is the same as saying that speeding at 100 mph is not illegal if the police do not arrest the driver or seek a court order against him. Compliance with federal law governing medical devices is mandatory regardless of whether the FDA says *anything* to confirm its application to a particular device or pursues enforcement action against a violator.[5]

An antitrust plaintiff has the burden of showing that it had a legal right to pursue the activity that is the source of its alleged antitrust injury. *Modesto Irrig. Dist. v. Pac. Gas & Elec. Co.*, 309 F. Supp. 2d 1156, 1170 (N.D. Cal. 2004), *aff'd*, 158 F. App'x 807 (9th Cir. 2005). The existence or absence of such a right derives from the law itself, not from government enforcement of the law. For example, in *Modesto Irrigation District*, the court held that the plaintiff could not prove antitrust injury based on its inability to enter a market for which it lacked the necessary government clearance, thus "contravening controlling state law and attempting to derive income without attendant 'legal right.'" *Id.* Far from citing regulatory enforcement action, the court pointed to the plaintiff's lack of any right to "unilaterally" enter the market without government clearance – exactly the situation presented here. *Id.*; *see also Snake River Valley Elec. Ass'n v. PacifiCorp*, 357 F.3d 1042, 1050 n.8 (9th Cir. 2004) (no showing of antitrust injury possible where statute did not permit the activity without state approval). Plaintiffs had no legal right to hire someone like Rebotix to remanufacture EndoWrists without FDA clearance, and the fact that they were the proposed consumers of an unlawful service rather than a "competitor" (Pl. Rep. at 6) makes no difference. *See In re Canadian Imp. Antitrust Litig.*, 470 F.3d 785, 791-92 (8th Cir. 2006) (no antitrust injury to consumer plaintiffs because their inability to import prescription drugs was "caused by the federal statutory and regulatory scheme").

[5] Other than a dismissive footnote (Pl. Rep. at 9 n.9), plaintiffs have nothing to say about the fact that *United States v. Kaplan*, 835 F.2d 1199 (9th Cir. 2016), defeats their theory that the "commercial distribution" requirement creates a loophole for them. *See* CM at 17. Plaintiffs' cross-referenced briefing on this issue was fully responded to by Intuitive at Dkt. No. 174 at 7-8.

Moreover, the undisputed facts show that FDA *did* make its views known through official as well as unofficial means and *did* take action against Rebotix and Restore, warning both that they needed FDA clearance and should not continue operations without it. *See, e.g.*, Cahoy Dec. Exs. 23, 38. *And both companies ceased operating*. Restore informed FDA of its withdrawal and then hired Iconocare to develop a new process for which it recently obtained a limited FDA clearance. *Id.* Ex. 38 at -249, Ex. 39 at 204:16-205:17, 213:19-216:23. Regardless of the reason Restore and Rebotix made their choices, it is clear that FDA never needed to pursue additional enforcement action against them.

Plaintiffs cannot dispute that every FDA official who has ever addressed the question has identified the activity of modifying EndoWrist use counters as "remanufacturing" that requires FDA clearance. The most plaintiffs do is question the significance of some of FDA's statements. But plaintiffs offer no evidence that anyone at FDA has ever expressed a *different* view. Instead, plaintiffs rely on clearly inadmissible evidence from completely unofficial sources, such as double hearsay reports from a Deutsche Bank financial analyst who relied on interviews with unidentified persons he referred to as "experts" but admitted in his deposition that he did not know whether a medical device requires 510(k) clearance and could not identify anyone he had spoken to other than the owner of Restore and his lawyer. Pl. Rep. at 11-12 (citing Corrigan Exs. 77, 78; Spector Dec. (Dkt. No. 169-2) Ex. 125); Cahoy Supp. Dec. Ex. 97 at 48:7-19, 92:7-93:4, 128:4-16, 148:16-18, 194:23-195:2.[6]

Plaintiffs argue that FDA has not "issued a rule, guidance document, or any other *decision binding on the agency*" confirming that the law applies the same way to EndoWrists as it does to other devices. Pl. Rep. at 8. But even if this were true (it is not),[7] the statutes and regulations of general applicability remain in force. Existing law requires FDA clearance for modifications of medical devices

[6] Equally egregious is plaintiffs' citation of hearsay speculation from a Rebotix witness that he thought it was "clear" that FDA officials were "walking back" one communication from a "decision" to an "informal assessment." Pl. Rep. at 10. Even if this testimony were admissible – which it is not – it would not indicate that anyone at FDA believed this "assessment" was anything but correct.

[7] Some of the actions FDA has taken with specific reference to modification of EndoWrist use counters *have* come from senior officials and constitute "official" actions. These include an official letter sent to Rebotix, the clearance of the Iconocare 510(k) application (which requires Iconocare to label the EndoWrists it modifies as "remanufactured") and the creation of a separate official product code defining modified robotic surgical instruments with altered use limits as "remanufactured." *See* Cahoy Dec. Ex. 1 at ¶¶ 149–52 & Fig. 3, Ex. 35, Ex. 40, Ex. 41.

that significantly change their specifications, including FDA-cleared safety measures. That law cannot be ignored just because FDA has not issued a *separate* official policy statement confirming that the requirement applies to a particular device.[8]

In the end, plaintiffs resort to citing general policy discussions they interpret as showing that FDA has adopted a "cautious" general approach to regulating medical device "repair" for fear of imposing undue costs on hospitals. Pl. Rep. at 9-10. But the governing regulations are clear, as are their application to this activity. Tampering with an EndoWrist use counter is not mere "repair" under the regulations; it is remanufacturing that requires FDA clearance. And it is undisputed that no remanufacturer with a commercial offering has ever obtained such clearance. (Iconocare, which has a single limited clearance for one instrument, has not yet offered it commercially. Plaintiffs offer no evidence that Intuitive has impeded Iconocare from operating under this clearance.)

Plaintiffs' attempts to find support in Intuitive's recent activities are unavailing. Intuitive did, to be sure, believe that it was not required to provide a supplemental 510(k) submission when increasing the use limits for some X/Xi EndoWrists for which it already had clearance and could instead use a different regulatory process available to original manufacturers. FDA disagreed with this interpretation and required Intuitive to make a new 510(k) submission, which it promptly did. *See* Cahoy Dec. Ex. 1 ¶¶ 249-55; Cahoy Supp. Dec. Ex. 98. Plaintiffs make much of the fact that Intuitive, operating in a different regulatory context and in close communication with FDA (*see* Cahoy Supp. Dec. Ex. 103 at 27:1-29:20, 34:25-36:11, 39:15-41:13), continued to sell the instruments while that supplemental 510(k) submission was pending. But this says nothing about whether it would have been lawful for Rebotix and Restore to operate with no 510(k) clearance at all, when the regulations clearly required it and FDA was warning them not to operate without it. The only relevant fact emerging from this episode is that FDA is adamant that *no one* – including Intuitive – can change the use limits for an EndoWrist without separate 510(k) clearance.

[8] Plaintiffs' argument (Pl. Rep. at 7 n.6) that "there is no such thing" as a reusable device that is cleared for limited uses is simply wrong. FDA's final guidance on reprocessing reusable devices explicitly recognizes that such devices may have a limited number of uses and instructs manufacturers to develop appropriate means to ensure user compliance with such limitations. *See* FDA, REPROCESSING MEDICAL DEVICES IN HEALTH CARE SETTINGS: VALIDATION METHODS AND LABELING - GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF (2015), at 20 (www.fda.gov/media/80265/download).

Finally, plaintiffs complain about the timing of Intuitive's public statement confirming that its contracts do not prohibit use of remanufactured instruments that have FDA clearance. Pl. Rep. at 12. This public statement was made shortly after Iconocare obtained the first FDA clearance, and it is undisputed that no one had clearance before that. Intuitive's contracts allow use of instruments that are "approved" (*see, e.g.*, Cahoy Dec. Ex. 11 at -488), and plaintiffs cite no evidence that Intuitive ever told any customer it could not use FDA-cleared remanufactured instruments should they become available.[9] Moreover, contrary to plaintiffs' unsupported assertions, there is no evidence that FDA clearance is only a "modest hurdle" that third parties would have overcome earlier had Intuitive not done something (unidentified) to get in the way. Pl. Rep. at 7. The only record evidence is to the contrary: Rebotix tried and failed to get FDA clearance and then fought for years to convince FDA it did not need it. *See* CM at 7-8. Restore also resisted seeking clearance and only made the significant financial investment in Iconocare's efforts after FDA reaffirmed that it could not operate lawfully without clearance. *Id.* at 8-9. There is no evidence that Intuitive ever did *anything* to impede a third party in seeking FDA clearance or to prevent anyone from taking advantage of such clearance once obtained.

**2. Plaintiffs Had No Interest in Remanufactured EndoWrists.**

Plaintiffs are wrong in calling it undisputed that, absent the challenged restraints, Intuitive would have lowered EndoWrist prices and/or increased the use limits for all customers. Pl. Rep. at 13. There is no evidence of any such thing, and plaintiffs cite none other than the report of their retained expert. As discussed in Intuitive's *Daubert* briefs on that expert (Dkt. No. 126 at 2-3, 5-9; Dkt No. 181 at 1-5), he simply *assumes* there would have been enough market-wide demand for remanufactured instruments to affect Intuitive's prices for all customers; he is not a competent source of *evidence* that this assumption is accurate, and the purported evidence cited in his report does not support it. Nor do plaintiffs identify supporting evidence in their briefs on these motions. *See Brooke Grp. Ltd. v. Brown*

[9] Plaintiffs' citation to Intuitive's litigation settlement agreements with Restore and Rebotix (Pl. Rep. at 12) is plainly improper. *See* Fed. R. Evid. 408. But if those agreements could properly be considered, their real significance is that neither authorizes Rebotix or Restore to remanufacture EndoWrists without FDA clearance. Intuitive's position has been fully consistent at all times – it does not object to remanufacturing performed pursuant to FDA clearance; it continues to object to the remanufacture of its instruments and their use on patients without such clearance. The agreements appropriately refer to the process of adding lives to EndoWrists as "remanufacturing."

*& Williamson Tobacco Corp.*, 509 U.S. 209, 242-43 (1993) (expert's assertions cannot defeat summary judgment where they are not based on facts in the record); *City of Oakland v. Oakland Raiders*, 20 F.4th 441, 458-60 (9th Cir. 2021) (plaintiff could not show antitrust injury by relying on speculation about what would have happened in the absence of challenged restraints).

Absent clear proof of injury from market-wide impacts, plaintiffs have the burden of demonstrating that they had a contemporaneous interest in using remanufactured EndoWrists. *See* CM at 19 (citing cases). Plaintiffs attempt to explain away the deposition testimony of their own witnesses about their unwillingness to use medical devices that lacked required FDA clearance by suggesting that those witnesses only meant to refer to an instrument-specific *statutory* requirement imposed by "legislative intervention." Pl. Rep. at 13. But plaintiffs identify no testimony from those witnesses that says any such thing. Plaintiffs do not even attempt to explain the unequivocal testimony from Larkin's principal da Vinci surgeon that he viewed the Rebotix process as "shady" and was unwilling to use it without FDA clearance; the statement from the Franciscan official who received information on the Rebotix offering about her lack of interest in it; or the binding testimony from Valley Medical's corporate designee that it had no interaction with any remanufacturer. *See* CM at 12. No evidence cited in plaintiffs' Reply creates a genuine dispute of material fact on any of these points.

**3. Plaintiffs Cannot Claim Damages for X/Xi EndoWrists.**

Plaintiffs do not claim that anyone has ever had a commercial offering to reset X/Xi EndoWrists. Plaintiffs cite [redacted] (Pl. Rep. at 14-15), but they are unable to show a genuine dispute on the key *material* fact: that no one has yet completed those efforts. Plaintiffs' speculation that someone could have figured it out earlier with more financial resources is just that – speculation. They offer no *evidence* to that effect.

Plaintiffs' odd assertion that Intuitive's upgrading of the X/Xi system and its EndoWrists to use different encryption was "anticompetitive" does not change the result. The record shows that, consistent with FDA cybersecurity guidance, encryption was required for the X/Xi chip because it used enhanced wireless technology. *See* Cahoy Dec. Ex 8 at 109:6-110:23; Cahoy Supp. Dec. Ex 90; *id.* Ex. 91; *see also* Cahoy Dec. Ex 5 at 27:20–28:8 ("[W]e [switched to wireless] to ensure we had good consistency.

When you rely on electrical contacts, sometimes you could have inconsistencies on detection."). Plaintiffs' Reply does not come close to meeting the high bar they would face in pressing an antitrust challenge to product innovation, particularly given the testimony – including from plaintiffs' own witnesses – that hospitals upgraded to the Xi *because of* its enhanced technology. Cahoy Supp. Dec. Ex. 99 at 17:7–19:4; *id.* Ex. 100 at 44:19–45:16; *id.* Ex. 101 at 18:9–19:4; *id.* Ex. 102 at 12:21-13:16; *see also Allied Orthopedic Appliances Inc. v. Tyco Health Care Grp. LP*, 592 F.3d 991, 1000 (9th Cir. 2010) ("Absent some form of coercive conduct by the monopolist, the ultimate worth of a genuine product improvement can be adequately judged only by the market itself."). And plaintiffs still have no concrete evidence of antitrust injury relating to these instruments.

### C. Plaintiffs Have Failed to Demonstrate a Substantially Less Restrictive Alternative That Satisfies the Legitimate Justifications Intuitive Has Established.

Plaintiffs have no genuine answer to the fundamental problem that they cannot rest an *antitrust* claim on the mere existence of use limits for EndoWrists. An antitrust claim requires a showing of injury *to competition*, and the *only* competition plaintiffs claim should have occurred is the modification of Intuitive's own EndoWrists to *reset the use counters*. If there were no use counters, there would be nothing for a remanufacturer to reset to provide competition in the "but-for" world. Plaintiffs mention this point only in a footnote (Pl. Rep. at 16 n.15), where they speculate that in a "but-for" world with no use counters there might instead be third parties offering *other* kinds of unidentified "repairs" for longer-lived EndoWrists as they malfunctioned more often. (This footnote is notably silent on the implications of this scenario for patients.) But plaintiffs offer no evidence that any third party has ever contemplated offering any separate "repair" service – to the contrary, plaintiffs have stressed the fact that Rebotix *discarded* broken instruments and only offered its "service" on those that did not need real repair. *See* Dkt. No. 162 at 11. Customers almost never have any need for actual "repair" of EndoWrists, as Intuitive maintains a liberal return policy that allows customers to freely return any malfunctioning instruments. *See* Rosa Dec. ¶ 40.

Even if plaintiffs' attacks on the use limits had legal significance, those attacks cannot undermine the fact that the use limits, and the use counter that implements them, were cleared by FDA as critical elements of the showing of "safety and effectiveness" that allowed EndoWrists to be marketed

and used on patients – so important that FDA will not allow *anyone* to change them without new safety testing and FDA clearance. Plaintiffs' arguments about Intuitive's hopes that the products would be profitable cannot create a genuine dispute of material fact. *See USFL v. NFL*, 842 F.2d 1335, 1360-61 (2d Cir. 1988) (maximizing profits is not in itself an anticompetitive act, even for a monopoly). The product can only be profitable if it is in demand, and plaintiffs' own witnesses tout the superiority of the da Vinci system in comparison to other surgical modes based on the superior patient outcomes it offers. *See, e.g.*, Corrigan Ex. 4 at 11:7-25; Cahoy Supp. Dec. Ex. 99 at 15:6-16:6; *see also* Smith Dec. (Dkt. No. 153-6) Ex. 1 ¶¶ 107, 183-209.

Plaintiffs' statement that "there is no 'safety' exemption from the antitrust laws" is yet another straw-man argument. As the Ninth Circuit explained in *Epic Games*, the cases plaintiffs cite (Pl. Rep. at 17 n.16), which were also cited by Epic, stand only for the proposition that a defendant may not claim "that *competition itself* is ill-suited to a certain market or industry." 2023 WL 3050076, at *22. But courts regularly accept the justification that a restraint promoting safety makes the defendant's product more competitively attractive to consumers or satisfies regulatory requirements. *Id.* at *21 ("Antitrust law assumes that competition best allocates resources by allowing firms to compete on all elements of a bargain—quality, service, safety, and durability—and not just the immediate cost.") (internal marks and citation omitted); *Phonetele, Inc. v. AT&T Co.*, 664 F.2d 716, 737-78 (9th Cir. 1981) (recognizing antitrust defense based on "imperatives recognized as legitimate by the regulatory authority"). The use limits for EndoWrists, which were part of the FDA-cleared showing of safety and effectiveness required by the statute, and which promote the safety of the da Vinci system as an alternative to other modes of surgery, satisfy both of these independent tests. There is no genuine dispute of material fact about this.

The burden therefore shifts to plaintiffs to demonstrate the existence of a *substantially* less restrictive alternative to achieve the benefits realized by EndoWrist use counters. *Epic Games*, 2023 WL 3050076 at *24. And "[t]o qualify as substantially less restrictive, an alternative means must be virtually as effective in serving the defendant's procompetitive purposes … without increased cost." *Id.* (internal marks and citations omitted). In *Epic Games*, the court found the plaintiff's showing on its proposed alternatives, which were far more concrete than those presented by plaintiffs here, nonetheless lacked details necessary to establish the necessary equivalence of effectiveness and cost. *Id.* at *24-25.

Plaintiffs offer no evidence that it is even possible, much less equivalently so, to control the risk of overuse of EndoWrists through other means. Plaintiffs cite evidence that Intuitive has the ability to "monitor" certain information about the use of an instrument during surgery (Pl. Rep. at 18), but they offer no alternative use counter design that would use that data. And they offer no evidence that any such hypothetical alternative design would actually be "less restrictive" (i.e., would, on average, allow instruments to be used longer). Nor, since they have no *specific* alternative to offer, do they have evidence that it would be equally as effective in managing risk, and they do not even mention its cost.

Plaintiffs' other suggested alternative is to merely "educate" hospitals in how to evaluate the condition of each EndoWrist before it is used. This proposal is, again, entirely lacking in detail. How, for example, is a hospital supposed to be "educated" to know if microscopic degradation of tiny wire cables inside an instrument has reached the point of imminent failure? Plaintiffs do not say; nor do they offer evidence of the effectiveness or cost of additional hospital and surgeon training.

Plaintiffs' characterization of Intuitive's efforts to prevent circumvention of FDA-cleared requirements for the da Vinci systems and instruments as the "510(k) police" and "paternalistic" ignores the fact that all of the challenged conduct was specifically directed at ensuring that the instruments used with these highly regulated systems are in compliance with regulatory requirements, including the FDA-cleared use limits. EndoWrists are *part of* the da Vinci system; and if they are used outside their specifications, the whole system is outside specifications. It can surely have been no antitrust violation for Intuitive to inform customers of its concern that the remanufacture of instruments without FDA clearance was unsafe and unlawful. And contracts requiring only approved instruments to be used with the da Vinci system simply implemented Intuitive's ongoing responsibility to ensure that the systems to which the remanufactured instruments would be attached remained within approved safety parameters.

As the Ninth Circuit has cautioned, the "the proper role of antitrust courts is to accommodate the peculiar circumstances under which regulated entities operate." *Phonotele*, 664 F.2d at 742. FDA requires medical device manufacturers to take *ongoing* responsibility for the safe performance of their devices. *See* Rosa Dec. ¶ 30; *see also, e.g.*, 21 C.F.R. §§ 820.90, 820.100, 820.160, 820.198, 803.10, 803.50. Plaintiffs' suggestion that it would be a sufficient "alternative" for Intuitive to ignore tampering with its devices and simply leave it up to FDA to take enforcement action (Pl. Rep. at 18) ignores this

ongoing responsibility. And once again, plaintiffs fail to show that the result would have been an equally effective means of achieving the mandated level of safety and effectiveness.

**D. Plaintiffs' Speculative Assertions About Anticompetitive Effects and Injury to Themselves Are Insufficient to Support Their Claims About da Vinci Service.**

Plaintiffs' response to Intuitive's motion for summary judgment on their "da Vinci service" claims rests largely on attempted misdirection. A genuine dispute of material fact cannot be created by merely showing that customers would prefer to pay less – who does not? – and most of plaintiffs' cited evidence is simply to that effect. Plaintiffs offer no response at all to the binding testimony of plaintiff Larkin's corporate designee that it *would not use* a third-party servicer. Nor are they able to show that either of the other two plaintiffs had genuine interest in the highly degraded service offered by Restore, much less that they would have been willing to pay *extra* for it. *See* CM at 20-21 (citing testimony).[10]

Plaintiffs cannot create a genuine dispute of material fact by citing their expert's *assumption* that Intuitive would have dropped its prices for *all* service in the "but-for" world, even though the portion of the alleged market that was accessible to a competitor would have been tiny. As Intuitive has shown (CM at 20-21), only two percent of customers would have had any economic reason to consider using Restore's service – and Restore could fulfill only a fraction of those customers' needs. Plaintiffs' expert cannot himself purport to be a competent source of evidence on whether the tiny amount of business Restore could have captured would have had *any* material impact on price for everyone else, including these plaintiffs (who would not have been among Restore's potential customers). *Id.*; *see* Dkt. Nos. 126 at 12-13, 181 at 8. *Nothing* in the record supports this speculative assumption, which defies common sense. *See Brooke Grp. Ltd.*, 509 U.S. 209 at 242-43; *Oakland Raiders*, 20 F.4th at 458-60.

**E. Plaintiffs Have Failed to Establish That They Are Entitled to Partial Summary Judgment on Any Issue.**

Plaintiffs' short discussion in their Reply of their own summary judgment motion repeatedly asserts that Intuitive has conceded, or at least failed to dispute, points that Intuitive's Opposition and Cross-Motion clearly *did* dispute. This includes, for example, plaintiffs' assertion that "FDA has done

[10] Plaintiffs' suggestion that someone other than Restore might have entered to offer more competent competition is pure speculation. None of the cited evidence shows that any other entity was prepared to offer da Vinci service. And anyone who tried would have faced the same fundamental problem as Restore in lacking access to the proprietary software and tools required for most da Vinci service.

nothing to stop IRCs from repairing [*sic*] and resetting EndoWrists without 510(k) clearance" (Pl. Rep. at 21), which is both factually inaccurate and legally irrelevant. *See* pp. 2, 5-7 above.

Plaintiffs' Reply on its face makes clear that there are numerous disputed issues of material fact relating to their proposed market definitions and related allegations of market power. For example, on their contention that there is a separate relevant market for EndoWrist "replacement and repair [*sic*]," plaintiffs attempt to discount the testimony of their own witnesses about the absence of demand for remanufactured EndoWrists by calling it "hypothetical" and arguing that it can be discounted if the Court accepts, among other things, that FDA has not taken the position that clearance is required for remanufacturing of EndoWrists. Pl. Rep. at 22. As shown above, FDA unquestionably *has* taken that position. Plaintiffs argue that Intuitive treats EndoWrists as separate products from the rest of the da Vinci system, but they make no effort to confront the extensive contrary evidence. *See* CM at 26-27.

As the Ninth Circuit recently confirmed in *Epic Games*, an "aftermarket" exists as a *separate* relevant market only if, *inter alia*, the customer's obligation to purchase aftermarket items from the same seller is not disclosed at the time of the original purchase. 2023 WL 3050076, at *11-14. Given the language of the da Vinci purchase contracts (*e.g.*, Cahoy Dec. Ex. 11), plaintiffs cannot make this showing. And their claim that Intuitive has "concede[d]" it has monopoly power in a separate EndoWrist relevant market (Pl. Rep. at 24) ignores Intuitive's factual and legal showing that no such relevant market exists. CM at 26-29.

Finally, Plaintiffs' mere characterization of their argument about a so-called "MIRS" market as "overwhelming" (*id.*) cannot entitle them to summary judgment on that issue. Plaintiffs do not contest the admissibility of the substantial contrary evidence Intuitive has offered, including evidence that Intuitive competes with other surgical modalities, including on price. They merely want the Court to accept their evidence instead. But Intuitive's proffer of admissible evidence creating genuine issues of material fact precludes summary judgment on this issue. *Anderson*, 477 U.S. at 248.

## III. CONCLUSION

The Court should grant Intuitive's motion for summary judgment on plaintiffs' claims and deny plaintiffs' motion for partial summary judgment.

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